



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: 510-337-6700

Via Federal Express

Our Reference: 29-54434

May 11, 1999

Paul Pires
Westside Holsteins
818 Coastal Court
Los Banos, California 93635

WARNING LETTER

Dear Mr. Pires:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on April 28, 1999, by Food and Drug Administration (FDA) Investigator John A. Gonzalez have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On February 4, 1999, you consigned a cow (identified by USDA laboratory report number 398810) to be slaughtered for human food. This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this cow revealed neomycin in the kidney at 377.00 parts per million (ppm). Presently, the tolerance level for neomycin in the uncooked edible kidney tissues of cattle is 7.2 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions ...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.
2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.
3. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species.
4. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.
5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Biosol brand of neomycin sulfate within the meaning of Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(v), and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. Labeling for Biosol specifically states it is not for use in female dairy cattle twenty months of age or older. Your practice of allowing dairy cows to drink from a calf trough containing Biosol presents a possibility that illegal residues will occur and is likely the cause of the illegal residues found in the cow you sold for food use.

Failure to comply with the label instructions on drugs you use to treat your animals presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to an auction yard where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

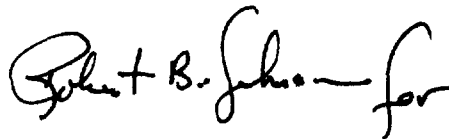
This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

Westside Holsteins
Los Banos, California

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Within fifteen (15) days of the receipt of this letter, notify our Fresno resident post office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to John A. Gonzalez, Investigator, United States Food and Drug Administration, 2202 Monterey Street, Suite 104 E, Fresno, California 93721.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "John A. Gonzalez for".

Patricia Ziobro
District Director
San Francisco District

cc:

A large, solid black rectangular redaction mark covering several lines of text.